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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,168	10/23/2001	Gregory L. Heacock	12726US02	7813

7590 12/28/2005

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EXAMINER	
WERNER, BRIAN P	

ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,168	HEACOCK, GREGORY L.	
	Examiner	Art Unit	
	Brian P. Werner	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 46-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30-39* is/are allowed.

6)☒ Claim(s) *1-29,40-44 and 46-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The following Office Action is responsive to the applicant's amendment and remarks received on October 14, 2005. Claims 1-44 and 46-55 remain pending.

Claim Objections

2. The previous claim objections are withdrawn in response to the amendment.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40-44

Rejections:

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kani et al. (US 4, 256,384 A) and Calder et al. (US 3,994,597 A).

Regarding claim 40, Kani discloses a retinal imaging device (figure 1; "retina" at column 1, line 55), comprising:

an illumination source illuminating the eye (numeral 22);

a lens through which light passes to illuminate the retinal and from which light is received from the retina (numeral 8); and

an image signal generator generating an image of the illuminated retina (numeral 14).

While Kani's light sources projects "visible light" (column 2, line 9), Kani does not teach a red and green LED combined to simultaneously illuminate the eye.

Calder discloses an optical sight with illumination, wherein the illumination source comprises red and green LEDs combined to simultaneously illuminate the eye as follows:

> "To obtain the required control of color in the illumination, pure light sources are needed. This is accomplished by using LED's (light emitting diodes) which have a stable monochromatic light output at any intensity. Three LED's 80, 82 and 84 are recessed into the front or outer end of block 74, the reflective coating 76 causing the entire light output to be directed by multiple reflections to the only outlet, the cavity 78. The LED's are selected to emit in the three primary colors, red, green and blue, which can be mixed to provide any desired color and white light."

Calder at column 3, lines 34-44

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize, as the light source required by Kani (i.e., numeral 22), the combined red and green LED illumination as taught by Calder, in order to provide "control of color in the illumination" (Calder column 3, line 34), and because LED's are more reliable, utilize less power and generate less heat than conventional incandescent bulbs such as those utilized by Kani.

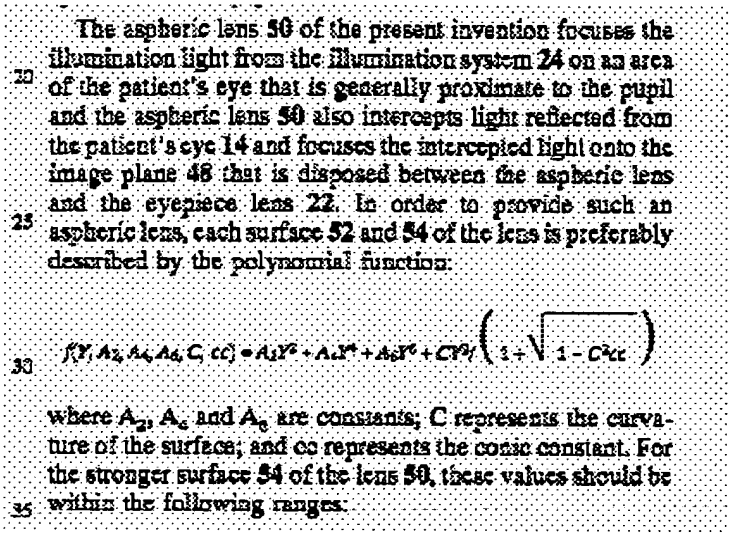
Regarding claim 41, Kani discloses and alignment system for aligning a user's eye along a predetermined axis and at a predetermined distance (numerals 18 and 19).

6. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kani et al. (US 4, 256,384 A) and Calder et al. (US 3,994,597 A), and further in combination with Heacock (US 5,861,938 A).

While Kani teaches an objective lens arrangement (numeral 8), Kani does not teach a lens with a aspheric surface as defined by claim 43, and in particular as defined by the equations f claims 42 and 44.

Heacock discloses a retinal imaging system (figures 1 and 2), comprising an aspheric objective lens system (figure 2, numeral 50; "The illumination light as it travels towards the patient's eye 14 is slightly diverging. The weaker surface 52 of the aspheric lens makes the slightly diverging illumination light parallel and directs the illumination light to the stronger surface 54 of the aspheric lens 50. The stronger surface 54 of the aspheric lens focuses the illumination light to a point 56 that is centered on the patient's pupil or generally proximate thereto. The illumination light continues its path until it strikes the retina 58 of the eye 14, thus

illuminating an area of the patient's eye within the boundaries of the rays 60 and 62" at column 5, line 35). Heacock's lens meets the requirements of claim 44 as follows (see Heacock column 6):



The aspheric lens **50** of the present invention focuses the illumination light from the illumination system **24** on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens **50** also intercepts light reflected from the patient's eye **14** and focuses the intercepted light onto the image plane **48** that is disposed between the aspheric lens and the eyepiece lens **22**. In order to provide such an aspheric lens, each surface **52** and **54** of the lens is preferably described by the polynomial function:

$$f(Y, A_2, A_4, A_6, C, cc) = A_2Y^2 + A_4Y^4 + A_6Y^6 + CY^2/\left(1 + \sqrt{1 - C^2cc}\right)$$

where A_2, A_4 and A_6 are constants; **C** represents the curvature of the surface; and cc represents the conic constant. For the stronger surface **54** of the lens **50**, these values should be within the following ranges:

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize, as the lens system required by Kani, the aspheric lens taught by Heacock as described above. One would be motivated to do so to facilitate close placement of the lens to the cornea ("final lens which can be positioned close to ... the cornea" at Rice column 4, line 27). That is, Heacock's lens "focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22" at Heacock column 6, line 20 and as depicted in figures 1 and 2. Thus, the lens of Heacock can be placed close to the cornea and can serve to illuminate the retina and also focus light reflected from the retinal back to the image plane making it a simple, single lens solution to Kani's lens

arrangement (i.e., numeral 8). One would also be motivated to utilize the Heacock lens because "the aspheric lens 50 produces a 60 degree field of view ... which is extremely wide" at column 6, line 68, where "the real image produced by the aspheric lens 50 is substantially free from distortions" at column 7, line 4.

Response to Arguments:

Applicant's remarks with respect to claims 40 and 41 at page 15 of the response are moot in view of the new grounds of rejection necessitated by the amendment.

Claims 46, 47, 48, 49, 50, 51, 52, 53 and 54

Rejections:

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 46, 47, 48, 50, 51, 52, 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Rice et al. (US 6,305,804 B1).

Regarding claim 53, Rice discloses:

directing light from an LED to illuminate the retina (figure 1, numeral 12; "laser diodes" at column 4, line 45);

directing light reflected from the illuminated retinal to an image signal generator (figure 1, numeral 11, 12 and 22);

generating at least one visual target viewable only when an eye is generally aligned along a predetermined axis ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63; the optical system as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis; likewise, the overall device itself has the same axis as depicted in figure 3; therefore, when the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system; stated another way, if the eye is placed too far above or below the horizontal axis, the "coaxial scene" cannot be viewed and the eye is not properly aligned; Refer to the response to arguments below);

determining alignment of the eye with the device ("the operator for initially locating the patient's retina, based on an image from the optical system in real time" at column 4, line 56); and

generating a signal representing an image of the retina when the eye is aligned (figure 1, numeral 22; figure 3, numeral 26 is the trigger; once the patient is looking at the target and the operator can see that the retinal is in the proper field of view, the trigger is pulled to capture an image).

Regarding claim 54, illumination is on the entire time while the patient is looking into the device, thus the illumination is on "after determining the eye is in alignment" and "before the image signal is generated" as required by the claim.

Regarding claim 50, Rice discloses:

directing light from an LED to illuminate the retina (figure 1, numeral 12; "laser diodes" at column 4, line 45);

directing light reflected from the illuminated retinal to an image signal generator (figure 1, numeral 11, 12 and 22); and

generating a visual target viewable only when an eye is generally aligned along a predetermined axis ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63; the optical system as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis; likewise, the overall device itself has the same axis as depicted in figure 3; therefore, when the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system; stated another way, if the eye is placed too far above or below the horizontal axis, the "coaxial scene" cannot be viewed and the eye is not properly aligned; Refer to the response to arguments below).

Regarding claim 51, Rice discloses:

directing light from an LED to illuminate the retina (figure 1, numeral 12; "laser diodes" at column 4, line 45);

directing light reflected from the illuminated retinal to an image signal generator (figure 1, numeral 11, 12 and 22);

generating a visual target viewable only when an eye is generally aligned along a predetermined axis ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63; the optical system as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis; likewise, the overall device itself has the same axis as depicted in figure 3; therefore, when the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system; stated another way, if the eye is placed too far above or below the horizontal axis, the "coaxial scene" cannot be viewed and the eye is not properly aligned; Refer to the response to arguments below);

determining alignment of the eye with the device ("the operator for initially locating the patient's retina, based on an image from the optical system in real time" at column 4, line 56); and

generating a signal representing an image of the retina when the eye is aligned (figure 1, numeral 22; figure 3, numeral 26 is the trigger; once the patient is looking at the target and the operator can see that the retinal is in the proper field of view, the trigger is pulled to capture an image).

Regarding claim 52, illumination is on the entire time while the patient is looking into the device, thus the illumination is on "after determining the eye is in alignment" and "before the image signal is generated" as required by the claim.

Regarding claim 46, Rice discloses:

directing light from an LED to illuminate the retina (figure 1, numeral 12; "laser diodes" at column 4, line 45);

directing light reflected from the illuminated retinal to an image signal generator (figure 1, numeral 11, 12 and 22);

generating a visual target viewable only when an eye is generally aligned along a predetermined axis ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63; the optical system as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis; likewise, the overall device itself has the same axis as depicted in figure 3; therefore, when the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system; stated another way, if the eye is placed too far above or below the horizontal axis, the "coaxial scene" cannot be viewed and the eye is not properly aligned; Refer to the response to arguments below);

determining when the eye is at a predetermined distance from the system ("the operator for initially locating the patient's retina, based on an image from the optical system in real time" at column 4, line 56; once the image is centered and in focus as adjusted by the focusing system,

the trigger at figure 3, numeral 26 is pulled to capture an image; if the user were not within an adequate distance from the device as predetermined by the optical system, then the image as viewed by the operator would not be in-focus and the device would require adjustment; for example, of the patient was three-feet away from the system, an in-focus image of the retina would be result and the operator would move the device closer to the eye; this distance adjustment is axiomatic to the system, as it is clear from the disclosure as a whole that the device must be near the pupil, or at least within a certain distance from the optical system in order for an in-focus image to appear on the screen).

Regarding claim 47, Rice discloses:

directing light from an LED to illuminate the retina (figure 1, numeral 12; "laser diodes" at column 4, line 45);

directing light reflected from the illuminated retinal to an image signal generator (figure 1, numeral 11, 12 and 22);

generating a visual target viewable only when an eye is generally aligned along a predetermined axis ("a coaxial 'scene' or visual target ... in the visual field" at column 4, line 59; "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63; the optical system as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis; likewise, the overall device itself has the same axis as depicted in figure 3; therefore, when the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system; stated another way, if the eye is placed too far above or below the horizontal axis,

the "coaxial scene" cannot be viewed and the eye is not properly aligned; Refer to the response to arguments below);

determining when the eye is at a predetermined distance from the system ("the operator for initially locating the patient's retina, based on an image from the optical system in real time" at column 4, line 56; once the image is centered and in focus as adjusted by the focusing system, the trigger at figure 3, numeral 26 is pulled to capture an image; if the user were not within an adequate distance from the device as predetermined by the optical system, then the image as viewed by the operator would not be in-focus and the device would require adjustment; for example, of the patient was three-feet away from the system, an in-focus image of the retina would be result and the operator would move the device closer to the eye; this distance adjustment is axiomatic to the system, as it is clear from the disclosure as a whole that the device must be near the pupil, or at least within a certain distance from the optical system in order for an in-focus image to appear on the screen) and

generating a signal representing an image of the retina when the eye is aligned (figure 1, numeral 22; figure 3, numeral 26 is the trigger; once the patient is looking at the target and the operator can see that the retinal is in the proper field of view, the trigger is pulled to capture an image).

Regarding claim 48, illumination is on the entire time while the patient is looking into the device, thus the illumination is on "after determining the eye is in alignment" and "before the image signal is generated" as required by the claim.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Miller et al. (US 6,690,466 B2).

Rice discloses:

an illumination source (figure 1, numeral 12);

a lens through which light passes to illuminate the retina, the lens receiving light reflected from the retina (figure 1, numeral 11); and

an image signal generator responsive to the reflected light to generate a signal representing an image or the illuminated retina (figure 1, numeral 22).

While Rice states, "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at column 4, line 43,

Rice does not teach the specific configuration of the light source, including "a red light emitting diode and a green light emitting diode ... combined to illuminate the eye" as required by claim 40.

Miller discloses an illumination system ("illuminator to illuminate a sample" at column 3, line 40), having use in a retinal imaging system as described in the 102 rejection above,

comprising a red light emitting diode and a green light emitting diode that combine to illuminate a sample ("provide light having any desired distribution of wavelengths across a broad range" where "all bands may be on, with precisely chosen amounts of light in each band" at column 3, lines 40-45; "Nineteen LEDs having wavelengths from 420-690 nm ..." at column 6, line 33; this spectrum covers the entire visual range, including red and green).

It would have been obvious at the time the invention was made to incorporate, as the illumination system required by Rice (e.g., Rice figure 1, numeral 12, the illumination system taught by Miller as described above. One would be motivated to do so in order to facilitate Rice's selection of frequency content using two or more lighting systems (i.e., "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at Rice column 4, line 43) by providing a multitude of light sources (e.g., nineteen LEDs at Miller column 6, line 33) that can provide "any desired distribution" (Miller, column 3, line 42) thus providing Rice with precise and accurate control over the illumination, where any frequency content desired can be achieved. Other benefits and advantages of the Miller system are describe throughout the Miller disclosure, including "simplicity and speed" at column 14, line 22.

Response to Arguments:

Summary of Applicant's Remark: "Each of claims 46-52 specifies generating a fixation target 'viewable only when an eye is generally aligned along a predetermined axis.' Neither Rice nor Kim disclose such a fixation target", and "because claims 53 and 54 also specify that the visible

target that is generated is viewable only when an eye is generally aligned along a predetermined axis, these claims are also believed to be allowable over the cited art as discussed above with respect to claims 46-52" at response page 16.

Examiner's Response: First, claims 46-48 and 50-54 are rejected as being anticipated by Rice alone – the Kim reference did not, and still does not play a part in these rejections. Second, Rice continues to anticipate the limitations of these claims. That is, Rice discloses generating a fixation target viewable only when an eye is generally aligned along a predetermined axis as follows. Rice generates "a coaxial 'scene' or visual target ... in the visual field" as described at column 4, line 59. Rice states that "the location of this visual target will bring the optic disk into the approximate center of the CCD detector" at column 4, line 63. The optical system of Rice as depicted in figure 1, including numerals 11, 12 and 22, has a horizontal axis. Likewise, the overall device itself has the same axis as depicted in figure 3. Figure 3 is reproduced herein below, overlaid with two optical axes A and B for discussion and visualization purposes. When the patient places his eye to view the "coaxial scene" as depicted at figure 3, numeral 10, the eye is aligned generally with the horizontal axis of the optical system as indicated by "Axis B". If the eye is placed too far above or below the horizontal axis indicated by "Axis A", the "coaxial scene" cannot be viewed and therefore the eye is not properly aligned. For example, if the eye is too low and therefore views an axis consistent with "Axis A", the user would not be able to view the "coaxial scene". Therefore, given that the coaxial scene can only be viewed when the eye 10 is placed in alignment with the optical system 11 as depicted in figure 3, the fixation target is

viewable only when an eye is generally aligned along a predetermined axis as required by the claims.

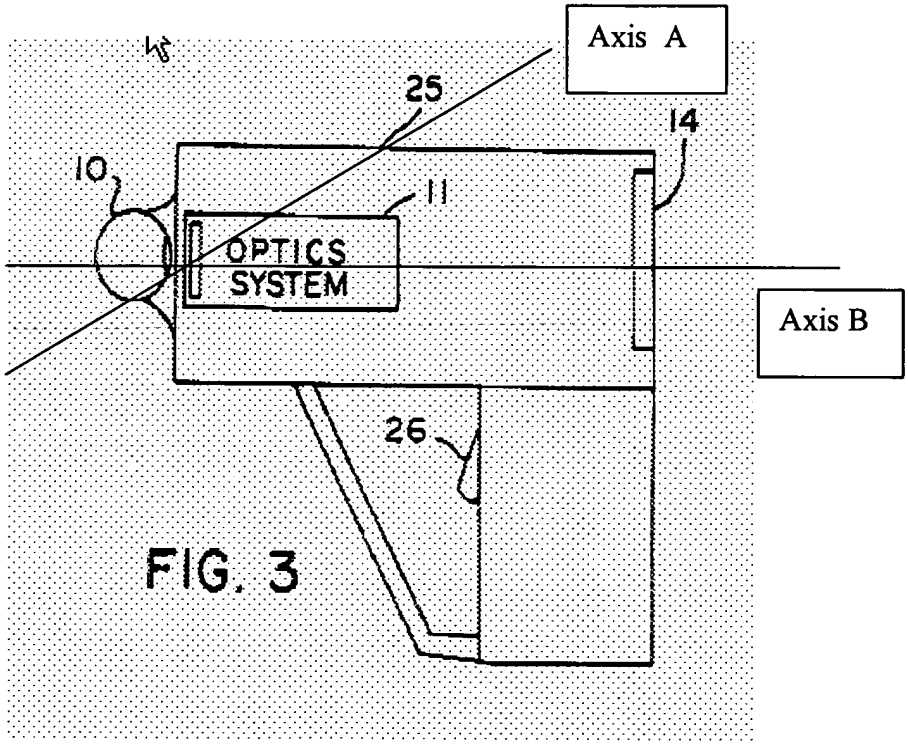


FIG. 3

Claim 55

Rejection:

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rice et al. (US 6,305,804 B1) and Miller et al. (US 6,690,466 B2) and Heacock (US 5,861,938 A).

Regarding claim 55, Rice discloses:

an illumination source (figure 1, numeral 12);

a lens through which light passes to illuminate the retina, the lens receiving light reflected from the retina (figure 1, numeral 11); and

an image signal generator responsive to the reflected light to generate a signal representing an image or the illuminated retina (figure 1, numeral 22).

While Rice states, "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at column 4, line 43,

Rice does not teach the specific configuration of the light source, including "a red light emitting diode and a green light emitting diode ... combined to illuminate the eye" as required by claim 40.

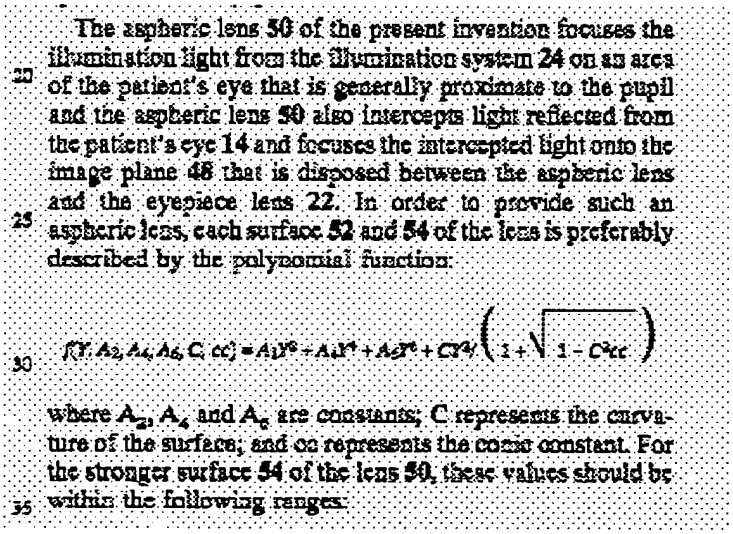
Miller discloses an illumination system ("illuminator to illuminate a sample" at column 3, line 40), having use in a retinal imaging system as described in the 102 rejection above, comprising a red light emitting diode and a green light emitting diode that simultaneously combine to illuminate a sample ("provide light having any desired distribution of wavelengths across a broad range" where "all bands may be on, with precisely chosen amounts of light in each band" at column 3, lines 40-45; "Nineteen LEDs having wavelengths from 420-690 nm ..." at column 6, line 33; this spectrum covers the entire visual range, including red and green).

It would have been obvious at the time the invention was made to incorporate, as the illumination system required by Rice (e.g., Rice figure 1, numeral 12, the illumination system taught by Miller as described above. One would be motivated to do so in order to facilitate Rice's selection of frequency content using two or more lighting systems (i.e., "the frequency content of this light source is selected dependent upon the compound to be analyzed", where "illumination light may be composed of two (or more) separate lighting systems" at Rice column 4, line 43) by providing a multitude of light sources (e.g., nineteen LEDs at Miller column 6, line 33) that can provide "any desired distribution" (Miller, column 3, line 42) thus providing Rice with precise and accurate control over the illumination, where any frequency content desired can be achieved. Other benefits and advantages of the Miller system are describe throughout the Miller disclosure, including "simplicity and speed" at column 14, line 22.

While Rice requires a lens system that includes a "final lens which can be positioned close to ... the cornea" at column 4, line 27,

Rice does not teach specific optical arrangements, including an aspheric surface.

Heacock discloses a retinal imaging system (figures 1 and 2), comprising an aspheric objective lens system (figure 2, numeral 50; "The illumination light as it travels towards the patient's eye 14 is slightly diverging. The weaker surface 52 of the aspheric lens makes the slightly diverging illumination light parallel and directs the illumination light to the stronger surface 54 of the aspheric lens 50. The stronger surface 54 of the aspheric lens focuses the illumination light to a point 56 that is centered on the patient's pupil or generally proximate thereto. The illumination light continues its path until it strikes the retina 58 of the eye 14, thus illuminating an area of the patient's eye within the boundaries of the rays 60 and 62" at column 5, line 35). Heacock's lens meets the following requirements (see Heacock column 6):



The aspheric lens **50** of the present invention focuses the illumination light from the illumination system **24** on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens **50** also intercepts light reflected from the patient's eye **14** and focuses the intercepted light onto the image plane **48** that is disposed between the aspheric lens and the eyepiece lens **22**. In order to provide such an aspheric lens, each surface **52** and **54** of the lens is preferably described by the polynomial function:

$$f(Y, A_2, A_4, A_6, C, cc) = A_2Y^2 + A_4Y^4 + A_6Y^6 + CY^2 \Big/ \left(1 + \sqrt{1 - C^2(cc)}\right)$$

where A_2, A_4 and A_6 are constants; C represents the curvature of the surface; and cc represents the conic constant. For the stronger surface **54** of the lens **50**, these values should be within the following ranges:

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize, as the "final lens system" required by Rice, the aspheric lens taught by Heacock as described above. One would be motivated to do so in order to fulfill Rice's requirement for a lens that can be placed close to the cornea ("final lens which can be positioned close to ... the cornea" at Rice column 4, line 27). That is, Heacock's lens "focuses the illumination light from the illumination system 24 on an area of the patient's eye that is generally proximate to the pupil and the aspheric lens 50 also intercepts light reflected from the patient's eye 14 and focuses the intercepted light onto the image plane 48 that is disposed between the aspheric lens and the eyepiece lens 22" at Heacock column 6, line 20 and as depicted in figures 1 and 2. Thus, the lens of Heacock can be placed close to the cornea and can serve to illuminate the retina and also focus light reflected from the retinal back to the image plane making it a simple, single lens solution to Rice's optical system which also serves to reduce the overall weight of the portable system disclosed by Rice (e.g., Rice figures 3 and 4). One would also be motivated to utilize the Heacock lens because "the aspheric lens 50 produces a 60 degree field of view ... which is extremely wide" at column 6, line 68, where "the real image produced by the aspheric lens 50 is substantially free from distortions" at column 7, line 4.

Response to Arguments:

Summary of Applicant's Remarks:

"The rejection of claim 55 in view of Rice, Miller and Heacock is respectfully traversed. Claim 55 requires simultaneously directing light from a green light emitting diode and a red light emitting diode to illuminate an area of a retina." As discussed above, Rice and Miller do not teach the simultaneous direction of green and red light to illuminate the retina but instead, teach the opposite, i.e. that the light from different light sources should be separated so that the light sources can be sequentially activated as opposed to simultaneously activated" at response page 16.

Examiner's Response: Miller teaches the simultaneous illumination from both red and green LEDs ("all bands may be on, with precisely chosen amounts of light in each band" at column 3, line 45).

Claims 1-29

Rejections:

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 16 have been amended to require alignment of the eye "along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being greater than 0° and less than 90°" (e.g., claim 1, lines 8-9). The original disclosure on the other hand describes alignment of the eye along an axis that is "approximately 14° with respect to the centerline 35 of the objective lens 16 and CCD camera 22" at specification page 8, line 3. The question arises as to whether the now claimed "greater than 0° and less than 90°" is supported by the originally disclosed "approximately 14°", and the examiner contends that it does not for the following reason. The entire purpose of the "approximately 14°" disclosed angle of the eye with respect to the lens is so that when "the individual sees the fixation target, the centerline 34 of the

target generator intersects the fovea 36 of the eye 20 and the optic disk 32 is substantially aligned with the centerline 35 of the lens 16 and CCD camera 22" as described at specification page 8, line 8. Angles of, for example, 1, 2, 3, 5, ... 87, 88, 89 degrees would not achieve the goal of fovea alignment. That is, an angle of one degree would be substantially parallel with the lens axis, and an angle of 89 degrees would be substantially perpendicular to the lens axis, neither of which would result in alignment of the fovea with the imaging axis. Not only would small angles of, for example, 1-5 degrees and large angles of, for example, 88 and 89 degrees not achieve the stated purpose of fovea alignment, but large angles such as 89 degrees would render the system non-functional because the eye would be pointing substantially downward, toward the ground, and the retina could not be imaged at all. Therefore, it is the examiner's contention that the applicant was not in possession of the full scope of the now claimed invention at the time of filing. The examiner suggests the following corrective language that is fully supported, and would overcome the art of record as well. Claim 1 will be used as an example:

From: "... an alignment system to align the eye along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being greater than 0° and less than 90° ...

To: "... an alignment system to align the eye along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being ~~greater than 0° and less than 90°~~ selected such that when the eye is in visual alignment with said axis, said centerline intersects the fovea, ..."

15. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alignment of the eye along an axis that is "approximately 14° with respect to the centerline 35 of the objective lens 16 and CCD camera 22" at specification page 8, line 3, does not reasonably provide enablement for alignment of the eye "along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being greater than 0° and less than 90°" (e.g., claim 1, lines 8-9). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Independent claims 1 and 16 have been amended to require alignment of the eye "along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being greater than 0° and less than 90°" (e.g., claim 1, lines 8-9). The original disclosure on the other hand describes alignment of the eye along an axis that is "approximately 14° with respect to the centerline 35 of the objective lens 16 and CCD camera 22" at specification page 8, line 3. The question arises as to whether the full scope of the now claimed "greater than 0° and less than 90°" is enabled by the original disclosure. That is, the original disclosure describes "approximately 14°" so that when "the individual sees the fixation target, the centerline 34 of the target generator intersects the fovea 36 of the eye 20 and the optic disk 32 is substantially aligned with the centerline 35 of the lens 16 and CCD camera 22" as described at specification page 8, line 8. Many angles falling within the now claimed range of "greater than 0° and less than 90°", for example, 1, 2, 3, 5, ... 87, 88, 89 degrees, would not and could not achieve this goal and would not even work. For example, 88 and 89 degree angles would place the alignment device

(i.e., figure 1, numeral 30) and the eye perpendicular to the lens axis. Therefore, the eye, if viewing the alignment device 30 at 89 degrees, would be pointing substantially downward, toward the ground, and the retina could not be imaged at all. Likewise for other angles within the now claimed range. Therefore, it is the examiner's contention that the invention would not work at all with certain angles of the now claimed range (e.g., 89 degrees), and therefore one skilled in the art would require undue experimentation to make and use the invention commensurate with the full scope of the claims. Refer to the written description rejection above for suggested corrections.

16. Independent claims 1 and 16, as well as their dependent claims, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action above, in such a was as to convey the distinguishing subject matter of an alignment system to align the eye along an axis that is at a predetermined angle with respect to a centerline of the lens, the angle being selected such that when the eye is in visual alignment with said axis, said centerline intersects the fovea.

Per specification page 8, first paragraph, "with such an arrangement, when the eye 20 is aligned with the system 10 such that the individual sees the fixation target, the centerline 34 of the target generator intersects the fovea 36 of the eye 20 and the optic disk 32 is substantially aligned with the centerline 35 of the lens 16 and CCD camera 22" and "because the illumination light is directed to a blind spot on the retina, the optic disk, the illumination light is not irritating to the user. This is opposed to prior retinal identification systems where the bright illumination light is focused on an area of the retina other than the optic disk and is perceived by the user.

This bright light can be irritating to the user. As such, the system 10 is more comfortable to use than prior retinal identification systems."

The prior art Rice et al. (US 6,305,804 B1), Kim et al. (US 6,594,377 B1) and Horiguchi et al. (US 6,490,365 B2) do not teach these limitations. Horiguchi does teach an eye imaging device ("eye image pickup device" at column 1, line 56) comprising an alignment system ("one person can determine the precise direction in which to move one's eye" at column 2, line 5). The alignment system includes an elongated channel (figure 6, numeral 9; "optical fiber cable 9" at column 4, line 61) having an end into which the user looks (figure 6, numeral 11) and a longitudinal axis at an angle with respect to a centerline of the lens (referring to figure 6, the longitudinal axis of numeral 9 is substantially 90 degrees w.r.t. the objective lens axis), a light disposed in the channel at a distance from the end into which the user looks (figure 6, numeral 10; "LED 10" at column 4, line 65) where the light is visible when the eye is aligned ("With this setting, when the light shielding portion 3 and the visible guide light 6 are viewed along the light axis 5 from the outside of the mirror barrel 8, they have the same appearance as the annular eclipse shown in FIG. 2(a)" at column 5, line 16). However, Horiguchi's alignment devices is substantially 90 degrees with respect to the lens optical axis as required by independent claims 1 and 16, and not straight as required by claim 16.

Response to Arguments:

Applicant's arguments on pages 12-14 of the response have been considered, and the prior art rejections withdrawn. However, new 112 rejections are advanced above.

Claims 4, 18 and 30-39

17. Claims 30-39 are allowed.

18. Claims 4, 18 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter: Independent claim 30 and dependent claims 4, 18 and 24, each of which define a retinal image capture system, distinguish over the prior art via. their claimed relationship between an alignment system and a distance detection system. That is, each recite an alignment system comprising an angled channel having a distal light source with first and second states, where the user looking into the channel is in proper alignment when the light is visible, and a distance detector that determines when the eye is within a predetermined distance from the capture system, where the light in the alignment system changes state when the eye is at the predetermined distance. That is, "the single LED 70 provides an indication to the user that the eye 20 is correctly aligned along the longitudinal axis 34 and is at a desired distance from the system 10" at applicant's specification page 13, line 25. This ensures that the user is notified when the proper distance (i.e., z-axis alignment) is achieved in a non-disruptive manner via. the same light source used for the x and y axis alignment. There is no suggestion in any of the above references and without improper hindsight for this combination of elements.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian P. Werner whose telephone number is 571-272-7401. The examiner can normally be reached on M-F, 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on 571-272-7695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian Werner
Primary Examiner
Art Unit 2621
Monday, December 19, 2005

BRIAN WERNER
PRIMARY EXAMINER